#14 Decl. w/attach 10.9.03

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Louis E. Henderson, *et al.*

Application No.: 09/431,607

Filed: November 1, 1999

For: METHOD FOR IDENTIFYING AND USING COMPOUNDS THAT INACTIVATE HIV-1 AND OTHER RETROVIRUSES BY ATTACKING HIGHLY CONSERVED ZINC FINGERS IN THE VIRAL NUCLEOCAPSID PROTEIN

Examiner: Shanon A. Foley

Art Unit: 1648

DECLARATION UNDER 37 CFR § 1.132

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

I, Louis E. Henderson, being duly warned that willful false statements and the like are punishable by fine or imprisonment or both, under 18 U.S.C. § 1001, and may jeopardize the validity of the patent application or any patent issuing thereon, state and declare as follows:

1. All statements herein made of my own knowledge are true and statements made on information or belief are believed to be true.

2. I am an employee of SAIC under contract to the National Cancer Institute at the National Institutes of Health in Frederick, Maryland, in the AIDS Vaccine Program.

3. A substantial part of my work focuses on viral zinc fingers as a target for antiviral chemotherapy. Accordingly, I am an expert in the field of the invention, including the biology of retroviruses and the inactivation of retroviruses using various chemical agents targeted against retroviral zinc fingers. My *Curriculum Vitae* is attached as Exhibit A.

4. I have reviewed and analyzed the above-referenced patent application, and I am familiar with the contents therein.

5. I have read the Office Action, dated March 25, 2003, received in the present case, and I have reviewed and analyzed the references cited therein by the Examiner.

6. It is my understanding that the Examiner has rejected claims 24-26, 28, and 29 under 35 U.S.C. § 102(a) as allegedly being anticipated by, or, in the alternative, under 35 U.S.C. § 103(a) as allegedly being obvious over Ryser *et al.* I am aware the Examiner alleges that "Ryser *et al.* anticipate an inactivated retrovirus that has been inactivated with 5,5'-dithiobis(2-nitrobenzoic acid) (DTNB)," and that "Applicant's inactivated retrovirus...reasonably appears to encompass disrupted zinc fingers that are indistinguishable from the reference's inactivated retrovirus." However, for the reasons set forth below, the Examiner's concerns are overcome.

7. Ryser *et al.*, *Proc. Natl. Acad. Sci. USA*, **91**:4559-4563. "Inhibition of human immunodeficiency virus infection by agents that interfere with thiol-disulfide interchange upon virus-receptor interaction."

   This reference teaches that the membrane-impermeant sulfhydryl reagent DTNB inhibits HIV infection by inhibiting the non-zinc finger-containing protein disulfide-isomerase (PDI) on the surface of the host cell. Because DTNB is membrane-impermeant, it cannot cross the viral envelope to reach and disrupt zinc finger-containing nucleocapsid proteins, so it does not inactivate the mature, infectious HIV virus.

   As such, contrary to the Examiner's statement, Ryser *et al.* do not teach an inactivated virus, as DTNB inhibits the PDI protein on the surface of the host cell, and does not in any way act directly on the mature, infectious retrovirus. On the other hand, the present invention refers to a mature retrovirus inactivated by means of direct disruption of viral nucleocapsid proteins. Therefore, it would not have been obvious or anticipated to use the compounds as claimed in the present invention to inactivate retroviruses by disrupting CCHC zinc finger nucleocapsid proteins.

8. It is my understanding that the Examiner has rejected claims 24-29 under 35 U.S.C. § 102(a) as allegedly being anticipated by, or, in the alternative, under 35 U.S.C. § 103(a) as allegedly being obvious over Williams *et al.* I am aware the Examiner alleges that the Aldrithiol-2 compound of the present invention has an identical CAS registry number to the bis(4-chlorophenyl) disulfide compound of Williams *et al.* However, for the reasons set forth below, the Examiner's concerns are overcome.

9. Williams *et al.*, PCT Application Publication No. WO 94/19321. "Inhibitors of HIV reverse transcriptase."

   This reference teaches the use of novel indole compounds for inhibiting HIV reverse transcriptase and preventing or treating HIV infection. However, neither Aldrithiol-2 nor bis(4-chlorophenyl) disulfide is an indole compound. In fact, contrary to the Examiner's allegation, the attached Exhibits B and C show that Aldrithiol-2 is clearly a different compound than bis(4-chlorophenyl) disulfide and that both are structurally different from the indole compound disclosed and claimed in Williams *et al.* Further, bis(4-chlorophenyl) disulfide is not claimed in Williams *et al.*, and is only used in Example 57 on page 109 as a component of the reaction to synthesize an indole compound of claim 1.

   Therefore, it would not have been obvious or anticipated to use Aldrithiol-2 to inactivate retroviruses by disrupting CCHC zinc finger nucleocapsid proteins, because the use of

Aldrithiol-2, a non-indole compound, to inactivate retroviruses as claimed in the present invention is neither taught nor suggested by Williams *et al.*

10. It is my understanding that the Examiner has rejected claims 24-26, 28, and 29 under 35 U.S.C. § 102(a) as allegedly being anticipated by, or, in the alternative, under 35 U.S.C. § 103(a) as allegedly being obvious over Levine *et al.* WO 93/15730. I am aware the Examiner alleges that "the method of Levine *et al.* comprising the compound [DTNB] and the HIV with a disabled viral protease anticipates a composition comprising an inactivated retrovirus since the compound inhibits the virus replication." However, for the reasons set forth below, the Examiner's concerns are overcome.

11. Levine *et al.* PCT Application Publication No. WO 93/15730. "Use of 5,5'-dithio-bis(2-nitrobenzoic acid) for inhibition of HIV protease."

    This reference teaches the use of DTNB to inhibit a purified recombinant viral protease. Examples 1 and 2 on pages 14-17 of Levine *et al.* demonstrate inhibition of recombinant HIV protease, and not of a mature, active retrovirus. As a result, Levine *et al.* do not teach inactivation of a mature, infectious retrovirus, but instead teach inhibition of a recombinant viral protease.

    The viral protease is responsible for cleaving the viral polyprotein into mature viral proteins. The protease is active when an immature viral particle, containing unprocessed polyprotein, buds from the host cell. After the protease cleaves the polyprotein, thereby converting the immature viral particle into a mature infectious retrovirus, the protease has completed its function. As such, protease inhibitors in general inhibit the viral protease inside the host cell so that when an immature particle buds from the cell, it remains inactive and never matures into an active retrovirus. As a result, ***the immature viral particle is never activated, thus rendering it incapable of being inactivated.*** Protease inhibitors do not inactivate mature, infectious retroviruses because the function of the protease has already been completed at this point. Therefore, Levine *et al.* teach viral protease inhibition on a recombinant viral protease, but provide no teaching or suggestion on how to inhibit a viral protease in a host cell or a viral particle, as DTNB is membrane impermeant.

    Moreover, Example 3 of Levine *et al.* (pages 17-18) sets forth a proposed therapeutic treatment for humans infected with HIV using DTNB. Because no data is shown and due to the fact that DTNB is a membrane-impermeant reagent, it seems highly unlikely that the use of DTNB on infected host cells could be an effective treatment strategy.

    Therefore, not only are the proteins targeted by Levine *et al.* and the present invention distinct (viral protease *vs.* nucleocapsid protein), but **the present invention acts on the mature, active retrovirus while Levine *et al.* acts on a recombinant viral protease.** As such, it would not have been obvious to use the compounds as claimed in the present invention to inactivate retroviruses by disrupting CCHC zinc finger nucleocapsid proteins.

12. It is my understanding that the Examiner has rejected claims 24, 28, and 29 under 35 U.S.C. § 102(a) as allegedly being anticipated by, or, in the alternative, under 35 U.S.C. § 103(a) as allegedly being obvious over Levine *et al.* WO 92/15329. I am aware the Examiner alleges that "Levine et al. anticipates an inactivated retrovirus that has been inactivated with a copper

ion delivery agent." However, for the reasons set forth below, the Examiner's concerns are overcome.

13. Levine *et al.* PCT Application Publication No. WO 92/15329. "Methods and pharmaceutical compositions for inhibiting protease from human immunodeficiency virus."

    This reference teaches the use of copper agents to inhibit a purified recombinant viral protease and parallels the teachings of Levine *et al.* WO 93/15730, as discussed above. As a result, Levine *et al.* do not teach copper agent-inactivation of a mature, active retrovirus, but instead teach copper agent-inhibition of a recombinant viral protease.

    Therefore, not only are the proteins targeted by Levine *et al.* and the present invention distinct (viral protease *vs.* nucleocapsid protein), but **the present invention acts on the mature, active retrovirus while Levine *et al.* acts on a recombinant viral protease**. As such, it would not have been obvious or anticipated to use the copper agents claimed in the present invention to inactivate retroviruses by disrupting CCHC zinc finger nucleocapsid proteins.

14. It is my conclusion that none of the above-reviewed references cited by the Examiner teaches or suggests the use of compounds claimed in the present invention to inactivate retroviruses. Thus, it would not have been obvious or anticipated at the time of the present invention to inactivate retroviruses by disrupting CCHC zinc finger nucleocapsid proteins using the claimed compounds.

The declarant has nothing further to say.

Louis E. Henderson

Louis E. Henderson, Ph.D.

Date 9/24/03

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PRINCIPAL INVESTIGATOR, VIRAL PROTEIN LABORATORY, AIDS VACCINE PROGRAM, SCIENCE APPLICATIONS INTERNATIONAL CORP./SAIC, NCI-FREDERICK CANCER RESEARCH AND DEVELOPMENT CENTER

EDUCATION

B.A.,	Chemistry, University of Omaha, 1956
Ph.D.,	Biochemistry, University of Colorado, 1965

BACKGROUND

1989 - Present	Senior Research Scientist, Viral Protein Laboratory (Protein Purification, Viral Mutagenesis, and Retroviral Protein Biochemistry Units), AIDS Vaccine Program, SAIC, NCI-Frederick Cancer Research and Development Center, Frederick, Maryland.
1976 - 1989	Senior Research Scientist, Immunochemistry Section, Laboratory of Molecular Virology and Carcinogenesis, ABL-Basic Research Program, NCI-Frederick Cancer Research and Development Center Frederick, Maryland.
1973 - 1976	Research Associate, Yale University, Department of Molecular Biophysics and Biochemistry, New Haven, Connecticut.
1968 - 1973	Research Associate, University of Goteborg, Goteborg, Sweden.
1965 - 1968	Postdoctoral Fellow, Harvard University, Department of Biology, Cambridge, Massachusetts.
1959 - 1965	Graduate Student, University of Colorado, Boulder, Colorado.

EXHIBIT

A

PROFESSIONAL RECOGNITIONS

1994 - Present	Editor for Human Retroviruses and AIDS
1992 - 1994	Adjunct Professor at University of MD, Baltimore Campus, Baltimore, MD.
1988 - Present	Graduate Thesis Research Advisor for Hood College, Frederick, MD
1988 - Present	Reviewer for Journal of Virology
1983 - Present	Reviewer for Analytical Biochemistry
1971 - 1973	Swedish Industrial Research Council Research Grant
1965 - 1968	U.S. Public Health Service Postdoctoral Fellowship
1969 - 1971	Swedish Medical Research Council Research Grant Fellowship
1968 - 1969	Nobel Visiting Scientist Fellowship

PROFESSIONAL ORGANIZATIONS

American Society for the Advancement of Science
American Society of Microbiology
Sigma Xi

LOUIS E. HENDERSON

PUBLICATIONS

Stevens, C.O., Henderson, L.E. and Tolbert, B.M. 1964. Radiation chemistry of proteins II: Enzymatic activity and deuterium exchange properties of lysozyme and chymotrypsin. Arch. Biochem. Biophys. *107*:367.

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Carlsson, U., Aasa, R., Henderson, L.E., Johnson, B.H. and Lindskog, S. 1975. Paramagnetic and fluorescent probes attached to buried sulfhydryl groups in human carbonic anhydrase. Application to inhibitor binding, denaturation, and refolding. Eur. J. Biochem. *52*:25-36.

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Henderson, L.E., Oroszlan, S. and Konigsberg, W. 1979. A micromethod for complete removal of dodecyl sulfate from proteins by ion-pair extraction. Anal. Biochem. *93*:153-157.

Henderson, L.E., Gilden, R.V and Oroszlan, S. 1979. Amino acid sequence homology between histone H5 and murine leukemia virus phosphoproteins p12. Science *203*:1346-1348.

Oroszlan, S., Copeland, T.D., Henderson, L.E., Stephenson, J.R. and Gilden, R.V. 1979. Amino-terminal sequence of bovine leukemia virus major internal protein: Homology with mammalian type C virus p30s. Proc. Natl. Acad. Sci. USA *76*:2996-3000.

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Henderson, L.E., Benveniste, R., Sowder, R., Copeland, T.D., Schultz, A.M. and Oroszlan, S. 1988. Molecular characterization of *gag* proteins from simian immunodeficiency virus (SIV_{Mne}). J. Virol. *62*:2587-2595.

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Gorelick, R.J., Henderson, L.E., Hanser, J.P. and Rein, A. 1988. Point mutants of Moloney murine leukemia virus that fail to package viral RNA: Evidence for specific RNA recognition by a "zinc finger-like" protein sequence. Proc. Natl. Acad. Sci. USA *85*:8420-8424.

LOUIS E. HENDERSON

PUBLICATIONS

Kung, H-F, Calvert, I., Khan, F.R, Huang, H.-P., Oroszlan, S., Henderson, L.E., Copeland, T.D., Sowder, R.C. and Wai, C. 1989. Phosphorylation of human interleukin-2 (IL-2). Molecular and Cellular Biochemistry *89*:29-35.

Rot, A., Henderson, L.E. and Leonard, E.J. 1989. *Staphylococcus aureus* derived chemoattractant activity for human monocytes. J. Leukocyte Biol. *45*:114-120.

Hizi, M., Henderson, L.E., Copeland, T.D., Sowder, R.C., Krutzsch, H.C. and Oroszlan, S. 1989. Analysis of *gag* proteins from mouse mammary tumor virus. J. Virol. *63*(6):2543-2549.

Benveniste, R.E., Raben, D., Hill, R.W., Knott, W.B., Drummond, J.E., Arthur, L.O., Jahrling, P.B., Morton, W.R., Henderson, L.E. and Heidecker, G. 1989. Molecular characterization and comparison of simian immunodeficiency virus isolates from macaques, mangabeys, and African green monkeys. J. Med. Primatol. *18*:287-303.

Gorelick, R.J., Nigida, S.M.Jr., Bess, J.W.Jr., Arthur, L.O., Henderson, L.E. and Rein, A. 1990. Noninfectious human immunodeficiency virus type-1 mutants deficient in genomic RNA. J. Virol. *64*(7):3207-3211.

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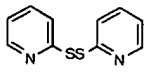
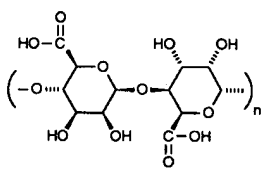
A2,830-9 ✓ ★	**Alginic acid** [*9005-32-7*] mp >300° *Merck Index* **12,**241 *SI* 81,D,7 *R&S* **1**(1),569O ..... *RTECS#* AZ5775000	5g 100g 500g	12.80 19.55 64.10
18,094-7 ★	**Alginic acid, sodium salt** [*9005-38-3*] (algin) *Merck Index* **12,**240 *FT-IR* **1**(2),1225B *Safety* **2,**93A *R&S* **1**(1),639C *RTECS#* AZ5820000 Powder. Viscosity 200-400 cps, 3% in water with sequestering agent	5g 100g 250g 500g	12.55 18.70 30.90 54.10



14,304-9



A2,830-9

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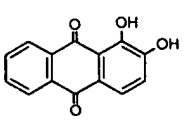
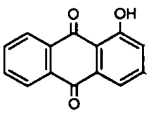
20,561-3 ★	**Aliquat® 336** [*5137-55-* $CH_3N[(CH_2)_7CH_3]_3Cl$ FW 6,404 **7,**380 *FT-IR* **1**(1),3 *RTECS#* BR8575000 *TO* Mixture of C_8 and C_{10} cha reagent[1] and a phase-tran 1537. *Proc. Symp. Solve Transfer Catalysis,* 3rd ed		
12,277-7 ✓ ★	**Alizarin** [*72-48-0*] (1,2-d λ*max* 609(567)nm *Beil.* **8,** *Safety* **2,**93C *R&S* **1**(2),1€ Dye content ~97% Biological stain Transition interval (acid): Transition interval (alkalin		
33,317-4 ★	**Alizarin,** tech., 85% [*72*		
23,403-6 ✓ ★	**Alizarin Blue Black B** λ*max* 548nm *FT-IR* **1**(2),5		
12,765-5 ✓ ★	**Alizarin Complexone d** anthraquinonyl)methyl *FT-IR* **1**(2),247A *SI* 294,E *RTECS#* AH0585000 For the colorimetric deter Dye content ~95%		
	Alizarin Cyanin Green		
	Alizarin Cyanone Gree		
11,996-2 ✓ ★	**Alizarin Red S monoh** 9,10-dioxo-2-anthrace *Beil.* **11,**355 *Merck Index UV-Vis* 80 *RTECS#* CB1 For gross staining of skel differentiating bone from indicator and in the analy 123. *Zoologica* **1934,** Dye content ~70%		
20,670-9 ✓ ★	**Alizarin Yellow GG** [*5* λ*max* 362nm *Beil.* **16,**24 *R&S* **1**(2),2741H *UV-Vis* Dye content ~ 50%		
	Alizarin Yellow R, see		
	Alkadride™ solution, s		
39,532-3 ★	**Alkali Blue 6B** [*30586-* λ*max* 603nm *SI* 442,C,1 Dye content ~50%		
42,052-2 ★	**ALKANOL® 189-S sur** *FLAMMABLE LIQUID* DuPont product		
42,054-9 ★	**ALKANOL® 6112 surf** DuPont product		



12,277-7



11,996

EXHIBIT

B

FOR LABO

DAVOS Solution Providers for Custom Chemistry

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Products and Technology

Davos' Product Pipeline

Davos Staff

Search Product Database

Upcoming Events

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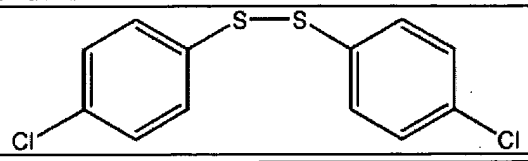
BIS(4-CHLOROPHENYL)DISULFIDE

Product Information



EXHIBIT

C